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EXAMINER	
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ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,418	ROSENQUIST ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 17, 2008 and July 10, 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53 and 56-68* is/are pending in the application.

4a) Of the above claim(s) *9-22,25-41,44, 46, 56-59 and 66-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,23,24,42,43,45,47-53 and 60-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

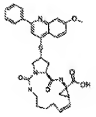
1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/20/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Responses to Election/Restriction filed on June 17, 2008 and July 10, 2008 are acknowledged. Claims 54-55 have been cancelled and new claims 57-68 have been added. Claims 1-53 and 56-68 are pending in this application.

Restriction

1. Applicant's election with traverse of Group I (claims 1-53) and the election of



species in the reply filed on June 17 and July 10, 2008 is acknowledged. The traversal is on the ground(s) that "Combinations of Different categories of claims, in pertinent part states that unity of invention shall be construed as permitting in particular the inclusion of the following combinations of claims of different categories in the same application: (A) in addition to an independent claim for a general product, an independent claim for a process and an independent claim for the use of said product…(5) a product, a process specially adopted for the manufacture of the said product and the use of the said product…As defined, and in accordance with the restriction requirement imposed in the office action, Group 1 is directed to a product; Group 2 is drawn to a method of using the compound; and Group 3 is directed to a method of manufacture of the product." Claim 55 has been cancelled, removing Group 3 (directed to method of manufacture of the product" from the Invention Groups.

Applicant's arguments have been fully considered but have not been found persuasive. Inventions 1 and 2 are patentably independent and distinct because claims 56 and 59 are drawn to a separate category of invention. Please note, claim 59 was inadvertently combined with Group 1, when it is clearly belongs to the method claims. The MPEP states the following regarding unity of invention of method claims: Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (PCT Rule 6.4). The examiner should bear in mind that a claim may also contain a reference to another claim even if it is not a dependent claim as defined in PCT Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, "Apparatus for carrying out the process of Claim 1 ...," or "Process for the manufacture of the product of Claim 1 ..."). Similarly, a claim to one part referring to another cooperating part, for example, "plug for cooperation with the socket of Claim 1 ...") is not a dependent claim (see MPEP 1850). Therefore, the method claims are in a different category: method of using the products. Therefore, these claims lack unity of invention. In regards to the species election traversal, the species are patentably independent and distinct due to many different variables that lead to different and independent structures for each species. There is no clear core structure, since each variable has different components that can lead to different structures. For example, if q is 3 and k is 1 then the compound of formula I would have

a 7 membered ring. However, if q is 1 and k is 1, then the compound of formula I would have a 5 membered ring. One would not anticipate the other. If R16 is H and G is O, this would not anticipate a compound wherein R16 is a C_6 alkyl and G is N-N. Furthermore, the search for each of the inventions is not co-extensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case.

The requirement is still deemed proper and is therefore made FINAL. Claims 55 and 59 are withdrawn from further consideration, pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention, there being no allowable generic or linking claim. Claims 9-22, 25-41, 56-58 and 66-68 have been withdrawn from further consideration, as being drawn to nonelected species. A search was conducted on the elected species, compound of Example 140, and this appears to be free of prior art. A search was extended to the broad Markush claim, and prior art was found. Claims 1-8, 23-24, 42-43, 45, 47-53, and 60-65 are examined on the merits in this office action.

Objections-Minor Informality

2. Claim 1 is objected to for the following minor informality: There appears to be an error in the claim. Claim 1 recites, "R^4 is =O, halo, amino, or OH; or R^4 and $R^{4'}$ together are =O..." The $R^{4'}$ should be corrected to $R^{4''}$ to be consistent with the rest of the application.

3. Claim 1 recites, "R^7 is C_1-C_6alkyl, C_0-C_3alkylC_3-C_7cycloalkyl, or C_2-C_6alkenyl…" There needs to be a comma in between C_0-C_3alkyl and C_3-C_7cycloalkyl.

4. Claim 24 is objected to for the following minor informality: There appears to be an error in the claim. Claim 24 recites, "...or optionally substituted C_o-C_3-alkylheterocyclyl." The "C_o" should be corrected to "C_0" to be consistent with the rest of the application.

5. Claim 45 is objected to for the following minor informality: There appears to be an error in the claim. Claim 45 recites, "…wherein R^7 and $R^{7'}$ together define…with $R^{7,a}$ wherein $R^{7'a}$ is…" The "$R^{7,a}$" should be corrected to "$R^{7'a}$" to be consistent with the rest of the application.

Rejection-35 U.S.C. 112, 2nd

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-8, 23-24, 42-43, 45, 47-53, and 60-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites that R^4 is =O, halo, amino, or OH; or R^4 and $R^{4'}$ together are =O..." Furthermore, claim also recites that "$R^{4'}$ is C_1-C_6alkyl, C_0-C_3alkylcarbocyclyl, C_0-C_3alkylheterocyclyl." It is unclear how R^4 and $R^{4'}$ together are =O when $R^{4'}$ is C_1-C_6alkyl, C_0-C_3alkylcarbocyclyl, C_0-C_3alkylheterocyclyl. Because claims 2-8, 23-24, 42-43, 45, 47-53 and 60-65 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

8. Claims 1 recites, "X is NRx- where Rx is H, C1-C5 alkyl or J; Rj is H and the other is H, C1-C5 alkyl or J…J, if present, is a single 3 to 10-membered saturated or partially unsaturated alkylene chain...to which R7 is attached to one of Rj, Rx, Ry or R11…Ry is H, C1-C3 alkyl or Ry is J." It is unclear from the claims what J is, because, the variables are referring back to another variable, which refers back to itself. In other words, the variable appears to be circular, without specifying what J is. Because claims 2-8, 23-24, 42-43, 45, 47-53 and 60-65 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

9. Claim 1 recites the limitation "the Formula I" in line 1 of claim 1. There is insufficient antecedent basis for this limitation in the claim. Formula I is mentioned for the first time in claim 1, therefore, Formula I recited in claim 1 lacks antecedent basis.

10. Claim 60 recites the limitation "the formula Ihe" in line 1 of claim 60. There is insufficient antecedent basis for this limitation in the claim. Formula Ihe is mentioned for the first time in claim 60, therefore, formula Ihe recited in claim 60 lacks antecedent basis.

Rejection-35 U.S.C. 112, 1st

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-8, 23-24, 42-43, 45, 47-53, and 60-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

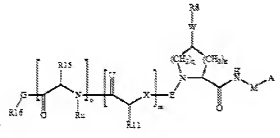
The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to a compound of the formula I

() having multitude of different variables. The generic formula I and variables do not describe a single structural feature, since there is no core structure being shared amongst the other compounds. The specification does not clearly define or provide examples of what qualify as compounds of the claimed invention.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is broad generics with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of compounds, since there is no common core structure. It must not be forgotten that the MPEP states that if a peptide is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the

specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives.

The specification is limited to compound that belong to the same class of compounds, those compounds all having a structure  . The working examples describe 157 Examples of compounds that share the common structure  . According to the broad generics of claim 1, there are multiple variables, and multiple components that are encompassed within those variables. The specification does not describe any other compounds having different variables for q and k or all other variables. There are multiple components and variables that would lead to vast numbers of different compounds of formula I. Description of compounds having the structure  is not sufficient to encompass numerous other compounds of formula I that belong to the same genus. For example, there are varying structural components, varying organic compositions and components, and numerous distinct qualities that make up the genus. Again, due to the lack of common core structure shared by the compounds of formula I, the specification does not describe sufficient amount of examples to encompass all of vast numbers of compounds encompassed by formula I. Furthermore, since there are variables within the variables, for example R16, G, R15, Ru, n, U, R11, m, E, W, R8, M, A, R1, R2, R3, R4 and so on, there are vast

numbers of compound possibilities of formula I. Therefore, there is not sufficient amount of examples provided to encompass the numerous characteristics of the whole genus claimed.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

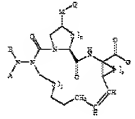
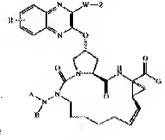
Rejection-35 U.S.C. 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-8, 23-24, 42-43, 45, 47-53, and 60-65 are rejected under 35 U.S.C. 102(a) as being anticipated by Wu et al (US Patent No. 7,125,845, filed in Jul 3, 2003 and issued Oct. 24, 2006).

15. Wu teaches a compound of Formula I (), or a pharmaceutically acceptable salt thereof, which inhibit serine protease activity of hepatitis C virus (HCV) NS-3-NS-4A protease (see abstract). Wu teaches that A is hydrogen, B is hydrogen, j is 0, n is 1, s is 1, M is O, and Q is substituted heterocycloalkyl (see column 3 and claim 1), meeting the limitation of claims 1-8, 23-24, 42-53 and 60-65. Wu further teaches that second-generation treatment involves co-treatment with antiviral nucleoside mimics like ribavirin (see column 1, lines 41-43, and claims 12-16). Wu further teaches a compound having the structure  (see Scheme 6, compound 6-2), that further anticipates claims 1-8, 23-24, 42-53 and 60-65. Wu teaches methods of treating an HCV infection in a subject by administering a pharmaceutical composition comprising the compounds (see abstract and claims 12-16).

16. Claims 1-8, 23-24, 42-43, 45, 47-53, and 60-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al (US Patent No. 7,125,845).

17. The teachings of Wu et al are described, supra.

Conclusion

18. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/J. H./
Examiner, Art Unit 1654